REMARKS

In the office action mailed on 03/11/2005: claims 11 – 20 were objected to because the Examiner stated that "the temperature sensor in claim 11 is not capable of providing closed loop operation by itself"; claim 9 was rejected under 35 U.S.C. § 112, second paragraph as being indefinite; claims 1, 2, 5 and 6 were rejected under 35 U.S.C. § 102(e) as being anticipated by Neuberger; claims 3 and 7 – 10 were rejected under 35 U.S.C. § 103(a) as being obvious over Neuberger in view of Fuller et al.; claims 11 – 15 and 18 – 20 were rejected under 35 U.S.C. § 103(a) as being obvious over Neuberger in view of Makower et al.; claims 16 and 17 were rejected under 35 U.S.C. § 103(a) as being obvious over Neuberger in view of Makower et al. and further in view of Fuller et al.; and claim 4 was objected to but is identified as containing allowable subject matter.

EXTENSION OF TIME

Applicants hereby petition for an extension of time under 37 C.F.R. § 1.136 to extend the time period for this amendment and response to the office action mailed on 03/11/2005. In particular, Applicants have enclosed herewith via check the payment to the commissioner for the required extension of time fees under 37 C.F.R. § 1.17(a).

CLAIM OBJECTIONS

Independent claim 11 is amended to overcome the Examiner's objection to the temperature sensor providing closed loop operation. The words "closed loop" have been deleted from claim 11. Claim 11 now simply recites an optical fiber including a temperature sensor at a distal end thereof for generating a temperature signal, to more particularly point out and distinctly claim the subject matter of Applicants' invention. It is believed that these amendments overcome the Examiner's reasons for objecting to claim 11.

CLAIM REJECTIONS – 35 U.S.C. § 112

Claim 9 is amended to overcome the Examiner's rejection as being indefinite in that the Examiner states that, "it is not clear how data is received (rather than generated based on calculations) by the processor." Claim 9 now recites that said processor updates said use parameters in response to a calculation by said processor and said processor compares said use parameters to a corresponding usage limit. This language has been amended to particularly point out and distinctly claim the subject matter of Applicants' invention. It is believed that this amendment overcomes the reasons for the Examiner's rejection of claim 9.

CLAIM REJECTIONS – 35 U.S.C. § 102

Claims 1, 5 and 6 have been amended and claim 2 canceled, without prejudice, to address Examiner's rejection. In particular, Examiner rejected claims 1, 2, 5, and 6 as being anticipated by Neuberger which discloses a medical radiation treatment system for identifying and monitoring the use of disposable or reusable optical fibers or other optical accessories. Neuberger indicates that the system is to prevent the use of overused or incompatible delivery devices by reading previously encoded information in the identification/recordation unit that provides all usage history, including number of uses or total duration of use.

Applicants' independent claim 1 has been amended to include, *generating a temperature signal using a temperature sensor* and *utilizing the temperature signal to determine whether at least one of said use parameters exceeds its corresponding usage limit.* The energy delivery device is disabled when the use parameter exceeds the usage limit. In a similar manner, Applicants' independent claim 5 has been amended to include, an optical fiber that includes *a temperature sensor at a distal end thereof for generating a temperature signal* and the optical fiber having a predetermined usage limit. Amended claim 5 also recites a processor for calculating a temperature from said temperature signal and for *utilizing said temperature signal in determining when said usage limit has been exceeded,* and said processor disabling the use of said energy delivery device when said usage limit has been exceeded.

Nowhere does Neuberger disclose or suggest any temperature sensor, let alone the generation of any temperature signal from the temperature sensor used in determining whether a usage limit has been exceeded. Consequently, amended independent claims 1 and 5 are patentable over Neuberger. Amended claim 6 depends from amended claim 5 and is therefore patentable over Neuberger for at least the same reasons as amended claim 5.

CLAIM REJECTIONS – 35 U.S.C. § 103

The Examiner has rejected claims 3 and 7 – 10 as being unpatentable over Neuberger in view of Fuller et al. The Examiner has also rejected claims 11 – 15 and 18 – 20 as being unpatentable over Neuberger in view of Makower et al. The Examiner has additionally rejected claims 16 and 17 as being unpatentable over Neuberger in view of Makower et al. and further in view of Fuller et al. In particular, claim 3 is a dependent claim that depends indirectly from amended independent claim 1; claims 7 – 10 are dependent claims that depend from amended independent claim 5; and claims 12 – 20 are dependent claims that depend from amended independent claim 11.

Neuberger discloses a medical radiation treatment system for identifying and monitoring the use of disposable or reusable optical fibers or other optical accessories. Neuberger indicates that the system is to prevent the use of overused or incompatible delivery devices by reading previously encoded information in the identification/recordation unit that provides all usage history, including number of uses or total duration of use. In addition, Fuller et al. discloses an apparatus having a non-volatile memory operatively associated with a conductor for storing a cumulative usage value wherein a circuit is provided which compares a cumulative usage value to a predetermined value representative of maximum usage. Fuller et al. also includes structure operatively associated with the circuit for preventing further use of the conductor when the updated cumulative usage value reaches the predetermined value. Nowhere does Neuberger or Fuller et al., either singly or in combination, disclose any temperature sensor, let alone any temperature sensor at the distal end of the optical fiber or temperature signal or temperature signal sent from the treatment site at the distal end of the optical fiber or the use of such temperature signal to disable the energy delivery device.

The Examiner indicates that Makower et al. teaches a medical treatment device with a temperature sensor on the distal end of the optical fiber (Fig. 10, # 46). In particular, Makower et al. simply discloses monitoring a temperature:

> During application of laser energy, it is necessary to monitor the temperature of surrounding tissue in order to prevent unwanted tissue damage. for this purpose, temperature sensing devices 46, such as thermocouples or miniaturized thermistors, are placed in appropriate locations along shaft 36, and also on cannula 12 as explained below. a person of ordinary skill in the art would have sufficient knowledge to provide the necessary connections to monitoring devices and the exact locations for the sensing devices. (Makower et al. at page 10) In order to monitor energy delivery and temperature, temperature sensing devices 46 are located along laser fiber 22 and cannula 12. In addition to thermocouples or thermistors as explained above, temperature sensing can be accomplished by fiber optic temperature sensors or infrared measuring along the cannula. Also, ultrasound may be used to measure temperature remotely by tissue characterization through signal processing of the ultrasound image. (Makower et al. at page 16)

Nowhere does Makower et al. disclose or suggest any temperature signal or the use of any such temperature signal, let alone a temperature signal sent from the treatment site at the distal end of the optical fiber or the use of such temperature signal in any calculation or the use of such temperature signal to disable the energy delivery device.

Amended claim 3 depends indirectly from Applicants' independent claim 1 which has been amended to include, *generating a temperature signal using a temperature sensor* and *utilizing the temperature signal to determine whether at least one of said use parameters exceeds its corresponding usage limit*. The energy delivery device is disabled when the use parameter exceeds the usage limit. In a similar manner, claims 7 – 10 depend from Applicants' independent claim 5 which has been amended to include, an optical fiber that includes *a temperature sensor at a distal end thereof for generating a temperature signal* and the optical fiber having a predetermined usage limit. Amended claim 5 also recites a processor for calculating a temperature from said temperature signal and for *utilizing said temperature signal in determining when said usage limit has been exceeded*, and said processor disabling the use of said energy delivery device when said usage limit has been exceeded.

Nowhere does Neuberger or Fuller et al., either singly or in combination, disclose or suggest any temperature sensor located at the treatment site (the distal end of the optical fiber). The Examiner indicates that Makower et al. discloses a temperature sensor, but Makower et al fails to disclose or suggest generating a temperature signal using a temperature sensor or utilizing the temperature signal to determine whether at least one of said use parameters exceeds its corresponding usage limit or utilizing said temperature signal in determining when said usage limit has been exceeded or updating at least one of said multiplicity of use parameters using said temperature signal. Consequently, neither Neuberger or Fuller et al. or Makower et al., either singly or in any combination thereof, discloses or suggests Applicants' invention as claimed in amended independent claims 1 and 5. Applicants believe that these claims are therefore patentable over Neuberger and Fuller et al. and Makower et al. and thus Applicants respectfully request withdrawal of these rejections and allowance of amended claims 1 and 5; and since claims 3 and 7 – 10 all depend either directly or indirectly from one of these amended independent claims, they are likewise patentable over Neuberger and Fuller et al. and Makower et al. for at least the same reasons. New dependent claim 21 similarly depends from amended independent claim 1, and is therefore patentable over Neuberger and Fuller et al. and Makower et al. for at least the same reasons as amended claim 1.

Moreover, regarding amended independent claim 11, Neuberger indicates at paragraph 5 that:

> It is important that disposable equipment not be used more than once and that equipment such as optical fibers be limited in their use so that they can be discarded before the level of degradation of the fiber, from repeated sterilization as well as irradiation, is severe enough to compromise treatment quality. It is further desirable that a device be able to guarantee only an approved number of uses, and is also useful to have a device that limits the use of a fiber depending on the amount of delivered energy used.

Neuberger is specifically focused on limiting overuse of the optical fiber in that it allows the system to record and retain information regarding the amount or duration of optical delivery device use or the amount of energy that has been conducted through such a device. Neuberger indicates that use of the device is when energy is conducted through the device. For example, in paragraph 36 Neuberger states the following: The use information encoded to the memory by

the transponder coil is distinguished between "full time use", where a full treatment was completed, "aborted use", "use for demonstrative purposes" or "use for calibration". In this way, the memory chip will contain accurate information as to the exact amount of energy that has been conducted in the fiber. Alternatively, the connector can ignore incomplete treatment and calibrations so as to only count completed treatments.

In contrast, claim 11 of Applicants' invention recites, wherein said multiplicity of use parameters include at least an elapsed time, a total treatment time, and a number of treatment sites. Applicants' elapsed time is effective covering all time spanning between activation through the running of the period of time regardless of whether any energy is conducted through the optical fiber or not. In particular, Applicants' indicate that the elapsed time is preferably computed based on identifying the time that the treatment was initiated. The exact date and time that the treatment was first initiated or alternatively the exact date and time that the energy delivery device was first initially activated is referred to herein as the baseline date and time respectively. The elapsed time is computed by subtracting the current or present time from the baseline date and time. In a similar manner, the treatment site is not necessarily a different patient but can simply be a separate treatment site within the same patient. Applicants' indicate that during the medical procedure, a number of different locations of the human tissue may need to be treated. Each of these locations is known as a treatment site.

Nowhere does Neuberger or Fuller et al. or Makower et al., either singly or in any combination thereof, disclose or suggest Applicants' invention as claimed in amended independent claim 11. Thus Applicants claim 11 is patentable over these references. In a similar manner, since claims 12 – 20 depend from independent claim 11, they are all as likewise patentable over Neuberger and Fuller et al. and Makower et al. for at least the same reasons.

Claim 4 has been amended to incorporate the features of the claims from which it depended in order to stand as an independent claim. Therefore amended independent claim 4 is allowable per the indications in the office action.

Upon entry of this amendment, claims 1 and 3 – 21 are pending in this application. Applicants respectfully submit that all of these claims currently pending in this application are in condition for allowance and respectfully request such an allowance of claims 1 and 3 - 21 by the Examiner.

It is believed that all of the pending claims have been addressed in this response. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhausted, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressly stated herein. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment or cancellation of any claim does not necessarily signify concession of unpatentability of any claim prior to its amendment or of any claim canceled.

Respectfully submitted,

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